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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/482,682	01/14/2000	Daniel J. Von Seggem	1294.0010001/RWE/LBB	7337

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EXAMINER

FOLEY, SHANON A

ART UNIT

PAPER NUMBER

1648

DATE MAILED: 03/12/2002

14

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/482,682

Applicant(s)

VON SEGGERN ET AL.

Examiner

Shanon A. Foley

Art Unit

1648

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 December 2001.
- 2a) ☒ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-69 and 71-99 is/are pending in the application.
- 4a) Of the above claim(s) 24-40, 42-46, 48-68 and 71-94 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 41 and 95-98 is/are allowed.
- 6) ☒ Claim(s) 1, 11, 22, 23, 47, 99 is/are rejected.
- 7) ☒ Claim(s) 2-10, 12-21 and 69 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☒ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 11. 6) ☐ Other: _____

Art Unit: 1648

DETAILED ACTION

Applicant has canceled claim 70, amended claims 4, 17, 41, 69, and added new claims 95-99.

Response to Amendment

fixed
The amendment filed 9/26/01 is objected to under 35 U.S.C. 132 because it introduces new matter into the disclosure. 35 U.S.C. 132 states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: priority claims to 09/795,292 is not supported by the original specification or declaration. The statement "The contents of each application are incorporated herein by reference" is also new matter since the only applications originally incorporated are: 09/423,783 and 60/115,920.

Applicant is required to cancel the new matter in the reply to this Office Action.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 22, 23, 47 and 99 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention for reasons of record.

Claim 22 still recites that the complementing cell line produces an adenovirus protein (emphasis added), but the claim concludes by stating that the cell line complements an adenovirus early protein gene and a fiber gene, which would be two proteins, not one denoted by

Art Unit: 1648

“an” at the beginning of the claim. To obviate this rejection, it is suggested that applicant delete “further...thereby” in lines 1-2.

Claim 23 vague and indefinite for the same reasons stated for claim 22. “Said gene under control of an inducible promoter” is vague and indefinite because there are two proteins complemented by the cell line, not one. Therefore, are both the early and the fiber gene under the control of the inducible promoter, or is only one gene under control of that particular kind of promoter?

Claim 47 is indefinite because it still depends from claim 46, which was withdrawn from consideration. This rejection can be obviated once the claim is amended to depend from claim 41.

Claim 99 is vague and indefinite because it cannot be determined what the structural and functional metes and bounds of what a “biologically active fragment” of a tumor-suppressive gene and/or a suicide protein are.

In response to a similar rejection against claim 70, applicant argues that one skilled in the art would understand these terms.

Applicant’s arguments have been considered, but are found unpersuasive. The specification does not define or teach what is considered to be a “biologically active fragment” of either a suicide protein or a tumor-suppressive gene. The skilled artisan would not be able to identify such a fragment without some teaching based on the structural and functional characteristics of the fragments. This rejection can be obviated once “biologically active fragments” have been deleted from the claim.

Art Unit: 1648

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1 and 11 are rejected under 35 U.S.C. 102(b) as being anticipated by Logan et al. (Proc. Natl. Acad. Sci. 1994; 81: 3655-3659) or in the alternative Sheay et al. (Biotechniques. 1993; 15 (5): 856-862).

The claim is drawn to a nucleic acid comprising an adenovirus TPL nucleic acid sequences comprising the first, second, and third TPL exons.

Logan et al. teaches that plasmid pJAW 43 encodes adenovirus type 2 tripartite leader sequences and plasmid pE1A-WT encodes rearranged E1A genes and 5' tripartite leader segments, see the first paragraph in the materials and methods section in column 1 on page 3655.

Sheay et al. teaches plasmid pRD112a, which encodes adenovirus type 2 tripartite leader sequences, see Figure 1.

Allowable Subject Matter

Claims 2-10, 12-21, and 69 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. Allowable subject matter is drawn to a nucleic acid sequence encoding different TPL exons.

Art Unit: 1648

Claims 41 and 95-98 are allowable over the prior art because the prior art does not teach or suggest a method for producing an adenovirus particle with a packaging cell line comprising the instant stably integrated nucleic acid.

Applicant's submission of an information disclosure statement under 37 CFR 1.97(c) with the fee set forth in 37 CFR 1.17(p) on 12/3/01 prompted the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 609(B)(2)(i). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shanon A. Foley whose telephone number is (703) 308-3983. The examiner can normally be reached on 9:00-5:30 M-F.


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on (703) 308-4027. The fax phone numbers for the

Art Unit: 1648

organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 308-4426 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.


Shanon Foley/SAF
March 8, 2002


JAMES HOUSEL 3/11/02
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600